



DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2022-0016]

Grant of Interim Extension of the Term of U.S. Patent No. 9,364,354; Reducer®

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of Interim Patent Term Extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension for a one-year interim extension of the term of U.S. Patent No. 9,364,354.

FOR FURTHER INFORMATION CONTACT: Ali Salimi by telephone at (571) 272-0909; by mail marked to his attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to his attention at (571) 273-0909; or by email to ali.salimi@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On April 8, 2022, Neovasc Medical Ltd., the patent owner of record, timely filed an application under 35 U.S.C. 156(d)(5) for a third interim extension of the term of U.S. Patent No. 9,364,354. The patent claims the catheter implantable device, Reducer[®]. The application for patent term extension indicates that a Premarket Approval Application (PMA) P190035 was submitted to the Food and Drug Administration (FDA) on December 31, 2019.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because there is a reasonable expectation that the regulatory review period will continue beyond the twice-extended expiration date of the patent, June 6, 2022, a third interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A third interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 9,364,354 is granted for a period of one year from the twice-extended expiration date of the patent.

Robert Bahr,
Deputy Commissioner for Patents,
United States Patent and Trademark Office.

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